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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,767	12/10/2003	Mitali Ghoshal	RDID 02010 US	6975

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ROCHE DIAGNOSTICS OPERATIONS INC.
9115 Hague Road
Indianapolis, IN 46250-0457

EXAMINER

HAQ, SHAFIQL

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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09/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/732,767	Applicant(s) GHOSHAL ET AL.	
	Examiner Shafiqul Haq	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 5-12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4 is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/10/03 & 5/9/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Election/Restrictions

1. Applicants' election without traverse of Group I, claims 1-4 and 13 filed October 17, 2006 in response to Office Action of September 20, 2006 is acknowledged and entered. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, claims 5-12 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited supra be canceled in response to this Office action to expedite prosecution.

2. Claims 1-4 and 13 are examined on merits.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable separately over each of Christ et al. (US 5,874,430), Rizza et al. (J. Med. Chem. 2002) or Patel et al. (Bioorg. Med. Chem. Lett. 1999).

Each of Christ et al., Rizza et al. and Patel et al disclose a number of Efavirenz derivatives and at least one of them are very similar to Efavirenz derivative of claim

13 of instant application. As for example the compounds taught by Christ et al. (see compounds 46 and 47 of table 1), Rizzo et al. (see compound s10 in Table 5, section B of page 2973,) and Patel et al. (see compound 4m of Table II in page 2809) are homologs of applicant's compounds. The difference between the claimed compound and that of the reference herein lie in the selection of hydrogen versus methyl group (i.e. H-O- versus CH₃-O-) on oxygen molecule at position 6 of the benzene ring of efavirenz derivative. It is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Wood*, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and *In re Lohr*, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963).

Similar compounds are expected to have similar properties and therefore, it would have been obvious at the time of the invention to a person of ordinary skill in the art to select common substituents such as alkyl, halogen, hydroxyl or alkoxy etc for "substituted aromatic moiety" with the expectation of producing similar compounds having similar properties.

The claimed compounds are so closely related structurally to the homologous compounds of the reference as to be structurally obvious therefore in the absence of any unobviousness or unexpected properties. Applicants should note that a generic teaching is grounds for 35 USC § 103 (a) obviousness type of rejection. In looking at the instant claimed compounds as a whole, the claimed compounds would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

Allowable Subject Matter

5. Claims 1-4 are allowable. The following is a statement of reasons for the indication of allowable subject matter: Prior art of record (US 2004/0214251 A1) discloses Efanvirnz derivatives wherein active ester, maleimido group, thiol and carrier are linked through nitrogen atom of heterocyclic oxazine ring (position 1) but fail to disclose or suggest such groups linked at position 6 of the aromatic ring of Efanvirnz derivative.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiquel Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1641



SHAFIQUL HAQ
EXAMINER
ART UNIT 1641



LONG V. LE 09/14/07
SUPERVISORY PATENT EXAMINER
ART UNIT 1641